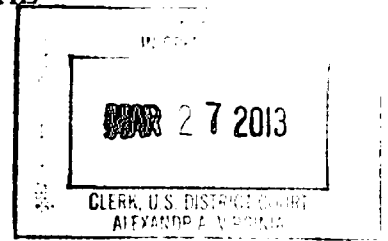


IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF VIRGINIA
Alexandria Division



UNITED STATES OF AMERICA)	UNDER SEAL
)	
)	Criminal No. 1:13CR130
v.)	
)	<u>Count 1:</u> 18 U.S.C. § 371– Conspiracy
)	
)	<u>Counts 2-3:</u> 18 U.S.C. § 545 – Importation
GALLANT PHARMA)	Contrary to Law
INTERNATIONAL INC.,)	
TALIB KHAN,)	<u>Counts 4-8:</u> 21 U.S.C. § 331(a) – Introduction
SYED HUDA (a/k/a “Farhan Huda”),)	of Misbranded Drugs
DEEBA MALLICK,)	
MUNAJJ ROCHELLE,)	<u>Counts 9-13:</u> 21 U.S.C. § 331(t) – Unlicensed
ROBERT WACHNA,)	Medical Wholesaling
HARVEY WHITEHEAD,)	
PATRICIA DURR,)	<u>Counts 14-15:</u> 18 U.S.C. § 1343 – Wire Fraud
LISA CORONITI,)	
MIRWAISS AMINZADA, and)	<u>Counts 16-17:</u> 18 U.S.C. § 1957(a) – Monetary
ANOUSHIRVAN R. SARRAF,)	Transactions With Criminally Derived Proceeds
)	
Defendants.)	<u>Notice of Forfeiture</u>

INDICTMENT

MARCH 2013 TERM - at Alexandria, Virginia

THE GRAND JURY CHARGES THAT:

GENERAL ALLEGATIONS

At all times relevant to this Indictment:

1. The Food and Drug Administration (“FDA”) was the agency of the United States responsible for regulating the manufacture, labeling, and distribution of drugs in the United States. Among other things, the FDA was responsible for enforcing the provisions of the Federal

Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (“FDCA”), including regulating the wholesale distribution of prescription drugs.

2. A “drug” was defined by the FDCA as, among other things, any article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; articles (other than food) intended to affect the structure or any function of the body of man or other animals; and articles intended for use as a component of any such articles. *See* 21 U.S.C. § 321(g).

3. A “biological product” was defined by the Public Health Service Act (“PHSA”) as “a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound) applicable to the prevention, treatment, or cure of a disease or condition of human beings.” 42 U.S.C. § 262(i). A biological product could be classified as a drug, depending on its mode of action and intended use. The FDCA applied to biological products subject to regulation under the PHSA. *See* 42 U.S.C. § 262(j).

4. A prescription drug was defined by the FDCA as “a drug intended for use by man which because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe except under the supervision of a practitioner licensed by law to administer such drug.” 21 U.S.C. § 353(b)(1)(A). A drug may also be limited to prescription use by its FDA-approved application. *See* 21 U.S.C. § 353(b)(1)(B).

5. The distribution of prescription drugs in the United States was regulated by the FDA and was subject to a series of strict controls. To prevent prescription drug diversion and the

introduction of counterfeit, stolen, or substandard drugs into interstate commerce, Congress enacted the Prescription Drug Marketing Act ("PDMA"), which it incorporated into the FDCA.

6. Under the PDMA, no person could engage in the wholesale distribution in interstate commerce of prescription drugs in a State unless such person was licensed by the State. *See* 21 U.S.C. §§ 353(e)(2)(A). FDA regulations set forth the minimum standards, terms, and conditions for the state licensing of wholesale prescription drug distributors, including guidelines for the storage and handling of such drugs and for the establishment and maintenance of records regarding the distributions of such drugs. *See* 21 U.S.C. § 353(e)(2)(B); 21 C.F.R. §§ 205.5, 205.50, 206.6. The regulations further provided that wholesale prescription drug distributors were required to permit State licensing authorities and authorized Federal, State, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures. 21 C.F.R. § 205.50(i).

7. The PDMA also required that each person engaged in the wholesale distribution of prescription drugs who is not the manufacturer or authorized distributor of record of such drug shall have provided to the person who receives the drug, before each wholesale distribution, a statement identifying each prior sale, purchase, or trade of such drug (including the date of the transaction and the names and addresses of all parties to the transaction). *See* 21 U.S.C. § 353(e)(1)(A). This is known as the "pedigree" requirement.

8. Before a new drug could be introduced into interstate commerce, it must have been the subject of an approved application filed with the FDA. *See* 21 U.S.C. § 331(d), 355(a). FDA approval was not for the molecular entity itself (i.e. the active ingredient) but included the labeling. *See* 21 C.F.R. § 314.50(i).

9. The FDCA prohibited the introduction, and delivery for introduction, into interstate commerce of any drug that was misbranded. *See* 21 U.S.C. § 331(a).

10. A drug was misbranded if, among other things, its labeling lacked adequate directions for use. *See* 21 U.S.C. § 352(f)(1). By regulation, the FDA defined “adequate directions for use” to mean directions “under which the *layman* can use a drug safely and for the purpose for which it is intended.” 21 C.F.R. § 201.5 (emphasis added). Prescription drugs could never contain adequate directions for lay use and were therefore misbranded unless they qualified for an exemption. A prescription drug was exempt from Section 352(f)(1) if (1) the drug was in the possession of a person regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale distribution of prescription drugs; and (2) the labeling on or within the package from which the drug was to be dispensed bore the statement “Rx Only” and was the labeling authorized by the FDA-approved new drug application. *See* 21 C.F.R. §§ 201.100 (a)(1)(i), (b)(1), (c)(2).

11. The United States Customs and Border Protection (“CBP”), and Immigration and Customs Enforcement, Homeland Security Investigations (“ICE-HSI”), two agencies within the United States Department of Homeland Security (“DHS”), were the federal agencies responsible for administering and enforcing violations of the laws governing the importation into the United States of goods and merchandise, including drugs.

GALLANT PHARMA

12. Defendants TALIB KHAN, SYED HUDA, DEEBA MALLICK, MUNAJJ ROCHELLE, HARVEY WHITEHEAD, ROBERT WACHNA, PATRICIA DURR, LISA CORONITI, MIRWAISS AMINZADA, and ANOUSHIRVAN R. SARRAF, and others known and unknown to the Grand Jury, were associated with GALLANT PHARMA

INTERNATIONAL INC. (“GALLANT PHARMA”), a company engaged in the illegal importation and sale of misbranded drugs in the United States. Between August 2009 and November 2011, the Defendants generated at least \$3.3 million from the sale of misbranded drugs to at least 54 doctors, medical practices, and hospitals in the United States.

13. GALLANT PHARMA maintained a website at www.gallantpharma.com, which represented that GALLANT PHARMA was a wholesale distributor of “Brand Name and Generic products” for cosmetic surgery, plastic surgery, dermatology, pain management, neurology, anesthesiology, and oncology. The website directed visitors to submit a web-based inquiry form to obtain a full product list. The website stated that GALLANT PHARMA provided customers with free next-day shipping via Federal Express (“FedEx”), and accepted payment via credit card, wire transfer, check and money order.

14. From in or about August 2009 until at least March 2013, GALLANT PHARMA illegally imported and sold at least the following drugs:

<i>Product</i>	<i>Use</i>
Alimta	Injectable chemotherapy for lung cancer
Anzemet	Anti-nausea treatment for surgery and chemotherapy patients
Botox	Injectable treatment for forehead wrinkles and eye muscle disorders
Dysport	Injectable treatment for forehead wrinkles and abnormal head position/neck pain
Eloxatin	Injectable chemotherapy for colorectal cancer
Faslodex	Injectable chemotherapy for breast cancer
Gemzar	Injectable chemotherapy for breast, lung, pancreatic, and ovarian cancer
Herceptin	Injectable chemotherapy for breast cancer
MabThera	Injectable chemotherapy for non-Hodgkin’s lymphoma
Taxotere	Injectable chemotherapy for lung and breast cancer
Velcade	Injectable chemotherapy for multiple myeloma patients who have already had several unsuccessful courses of treatment
Xeomin	Injectable treatment for cervical dystonia and blepharospasm
Zometa	Injectable treatment for bone tumors and hypercalcemia

15. GALLANT PHARMA was not licensed as a prescription drug wholesaler by the Commonwealth of Virginia.

16. At times, sales by GALLANT PHARMA were conducted under the name of Harmanda LLC. Harmanda was not licensed as a prescription drug wholesaler by the State of Michigan or the Commonwealth of Virginia.

17. Members of the conspiracy arranged for foreign co-conspirators to ship drugs intended for GALLANT PHARMA to the United Kingdom and Canada. Co-conspirators in the United Kingdom and Canada then shipped the drugs to the United States using Royal Mail and Canada Post. The Royal Mail and Canada Post both feed into the United States Postal Service ("USPS") for delivery in the United States and are generally subjected to less scrutiny by CBP than shipments arriving from other countries.

18. Co-conspirators in the United Kingdom and Canada would also break large packages into several smaller packages before sending to the United States. The packages would be accompanied by Customs declarations that would include misleading information about the shipment, such as an understated dollar value or a misleading description of contents. Many packages were addressed and delivered to Defendant ANOUSHIRVAN R. SARRAF at his medical practice in McLean, Virginia, in the Eastern District of Virginia, rather than to GALLANT PHARMA.

19. The Defendants established an account with at least one credit card merchant processor in the United States, Elevon, which collected sales revenue from GALLANT PHARMA customers on GALLANT PHARMA's behalf. Members of the conspiracy misrepresented to Elevon that GALLANT PHARMA sold medical supplies such as pillows, gowns, and patches.

20. Members of the conspiracy represented to Elevon that GALLANT PHARMA was a Canadian company and directed Elevon to deposit sales proceeds directly into Canadian bank

accounts. Members of the conspiracy also paid GALLANT PHARMA expenses in the United States with a check drawn on one of those Canadian bank accounts. In actuality, however, at all times relevant to this Indictment, GALLANT PHARMA was headquartered in the Eastern District of Virginia.

Defendants

21. Defendant GALLANT PHARMA was a corporation engaged in the illegal importation of misbranded drugs for distribution and sale to doctors, medical practices, and hospitals in the United States. GALLANT PHARMA was registered under the laws of Canada on or about August 29, 2009. The registered agent of GALLANT PHARMA was Defendant SYED HUDA, under his commonly used name "Farhan Huda", at an address in Oakville, Ontario. GALLANT PHARMA had two directors: Defendant SYED HUDA and an unindicted co-conspirator. GALLANT PHARMA's United States business was headquartered at the apartment of Defendants SYED HUDA and DEEBA MALLICK, in Crystal City, Virginia, in the Eastern District of Virginia. From on or about June 15, 2012, until at least March 2013, GALLANT PHARMA leased office space in Springfield, Virginia, in the Eastern District of Virginia.

22. Defendant TALIB KHAN, a citizen of Canada and a resident of Canada and Barbados, was a principal of GALLANT PHARMA. KHAN was the primary person engaged in sourcing foreign drugs for importation into, and sale in, the United States.

23. Defendant SYED HUDA, also known as "Farhan Huda", a citizen of Canada and a resident of Crystal City, Virginia, in the Eastern District of Virginia, was another principal of GALLANT PHARMA. HUDA had primary responsibility for GALLANT PHARMA's day-to-day operations in the United States. GALLANT PHARMA's United States headquarters were

located at HUDA's apartment in Crystal City, Virginia, in the Eastern District of Virginia. From on or about June 15, 2012, until at least March 2013, HUDA leased office space for GALLANT PHARMA in Springfield, Virginia, in the Eastern District of Virginia.

24. Defendant DEEBA MALLICK, a United States citizen and a resident of Crystal City, Virginia, in the Eastern District of Virginia, was the wife of HUDA, and resided with HUDA at GALLANT PHARMA's United States headquarters. MALLICK handled order shipment and payment processing for GALLANT PHARMA, and was also involved in sourcing drugs from foreign co-conspirators.

25. From in or about September 2009 until at least November 2011, Defendant MUNAJJ ROCHELLE, a dual citizen of Canada and the United States and a resident of Canada, was a sales representative for GALLANT PHARMA with primary responsibility for California. ROCHELLE was also involved in training new GALLANT PHARMA sales representatives.

26. Defendant ROBERT WACHNA, a citizen and resident of Canada, was a sales representative for GALLANT PHARMA, with primary responsibility for the Orlando and upstate New York regions.

27. From in or about July 2010 until at least March 2013, Defendant HARVEY WHITEHEAD, a United States citizen and resident of Michigan, was a sales representative for GALLANT PHARMA, with primary responsibility for Michigan. WHITEHEAD was also the owner of Harmanda, a limited liability company formed under the laws of Michigan on or about March 9, 2011.

28. From in or about September 2010 until at least March 2013, Defendant PATRICIA DURR, a United States citizen and resident of Florida, was a sales representative for

GALLANT PHARMA. At times, DURR had primary responsibility for the Boston, New York City, and Florida regions.

29. From in or about May 2011 until at least March 2013, Defendant LISA CORONITI, a United States citizen and resident of Pennsylvania, was a sales representative for GALLANT PHARMA, with primary responsibility for the Philadelphia region.

30. Defendant MIRWAISS AMINZADA, a United States citizen and resident of Canada, represented himself as the owner of Royal Canadian Imports and supplied misbranded drugs to GALLANT PHARMA.

31. Defendant ANOUSHIRVAN R. SARRAF, a United States citizen and resident of Rockville, Maryland, was a doctor and the owner of a medical clinic in McLean, Virginia, in the Eastern District of Virginia. SARRAF received importations in his and his clinic's name on behalf of GALLANT PHARMA, and purchased misbranded drugs from GALLANT PHARMA.

32. The above background allegations are re-alleged and incorporated into each Count of this Indictment as if fully set forth in each Count.

COUNT 1

(18 U.S.C. § 371 – Conspiracy)

THE GRAND JURY CHARGES THAT:

33. Beginning in or around August 2009, and continuing until at least March 2013, in the Eastern District of Virginia and elsewhere, the defendants,

GALLANT PHARMA,

TALIB KHAN,

SYED HUDA,

DEEBA MALLICK,

MUNAJJ ROCHELLE,

HARVEY WHITEHEAD,

ROBERT WACHNA,

PATRICIA DURR,

LISA CORONITI,

MIRWAISS AMINZADA, and

ANOUSHIRVAN R. SARRAF

did knowingly and intentionally combine, conspire, confederate, and agree, with each other and with other persons known and unknown to the Grand Jury, to:

(a) fraudulently and knowingly import and bring into the United States merchandise contrary to law, in violation of Title 18, United States Code, Section 545, specifically misbranded drugs in violation of Title 21, United States Code, Section 331(a);

(b) knowingly engage in the wholesale distribution in interstate commerce of prescription drugs in the Commonwealth of Virginia without being licensed by the Commonwealth of

Virginia to do so, in violation of Title 21, United States Code, Sections 331(t), 333(b)(1)(D), and 353(e)(2)(A);

(c) with the intent to defraud and mislead, introduce into interstate commerce misbranded drugs in violation of Title 21, United States Code, Sections 331(a) and 333(a)(2);

(d) knowingly and with the intent to defraud, devise and intend to devise a scheme and artifice to defraud, and to obtain money and property by means of false or fraudulent pretenses, representations, and promises, and, for the purpose of executing such scheme and artifice, transmit and caused to be transmitted wire communications in interstate and foreign commerce, in violation of Title 18, United States Code, Section 1343; and

(e) defraud the United States and its agencies by impeding, impairing, and defeating the lawful functions of the FDA to protect the health and safety of the public by ensuring that drugs distributed in the United States were safe and effective from the time of manufacturing to the delivery to the entity that sells or dispenses the product to the ultimate consumer or patient.

Ways, Manner, and Means of the Conspiracy

In furtherance of the conspiracy, the Defendants and others known and unknown to the Grand Jury employed, among others, the following manner and means:

34. It was part of the conspiracy that, beginning in or around August 2009, members of the conspiracy would purchase from foreign co-conspirators drugs intended for use in foreign countries.

35. It was further part of the conspiracy that foreign co-conspirators located in countries other than the United Kingdom and Canada would ship drugs intended for GALLANT PHARMA to members of the conspiracy in the United Kingdom and Canada, at the direction of members of the conspiracy.

36. It was further part of the conspiracy that members of the conspiracy in the United Kingdom and Canada would ship drugs intended for GALLANT PHARMA to the Eastern District of Virginia by Royal Mail and Canada Post, respectively. This method of shipment, and transshipment, furthered the conspiracy because it allowed packages to be delivered through the USPS with less scrutiny than would be applied to packages arriving from other countries.

37. It was further part of the conspiracy that members of the conspiracy in the United Kingdom and Canada would break packages intended for GALLANT PHARMA into multiple smaller shipments, or include misleading statements about the package contents and value, or send packages to a recipient other than GALLANT PHARMA. These actions furthered the conspiracy by misleading CBP and therefore causing CBP to apply lessened scrutiny to the packages.

38. It was further part of the conspiracy that members of the conspiracy addressed misbranded drugs intended for GALLANT PHARMA to Defendant ANOUSHIRVAN R. SARRAF at his medical practice in McLean, Virginia, in the Eastern District of Virginia.

39. It was further part of the conspiracy that, from in or about June 2012 until at least March 2013, members of the conspiracy leased office space in Springfield, Virginia, under the name of GALLANT PHARMA.

40. It was further part of the conspiracy that members of the conspiracy caused misbranded drugs to travel in interstate commerce from the Eastern District of Virginia to at least 54 distinct doctors, medical practices, and hospitals across the United States.

41. It was further part of the conspiracy that members of the conspiracy caused at least one credit card processor to establish a merchant account based on false statements, which

furthered the conspiracy by enabling members of the conspiracy to accept credit card payments for sales of misbranded drugs.

42. It was further part of the conspiracy that members of the conspiracy caused the proceeds of credit card payments to be transferred to bank accounts in Canada. Between April 2010 and January 2012, more than \$1.9 million was transferred by one Visa and Mastercard payment processor, Elevon, to Toronto Dominion Bank and Bank of Nova Scotia accounts held in the name of GALLANT PHARMA INTERNATIONAL INC. This furthered the conspiracy by concealing the conspiracy and its proceeds.

43. It was further part of the conspiracy that members of the conspiracy paid GALLANT PHARMA expenses from a bank account held in Canada.

44. It was further part of the conspiracy that members of the conspiracy deposited check payments from sales of misbranded drugs into a Capital One bank account in Arlington, Virginia, in the Eastern District of Virginia, held in the name of Defendant DEEBA MALLICK.

45. It was further part of the conspiracy that members of the conspiracy regularly communicated with each other via e-mail about the acquisition, illegal importation, and sale of misbranded drugs.

46. It was further part of the conspiracy that the conspiracy derived a direct financial benefit from the illegal importation and sale of misbranded drugs. Between August 2009 and November 2011, the Defendants generated at least \$3.3 million from the sale of misbranded drugs in the United States.

Overt Acts

47. It was further part of the conspiracy that the following acts in furtherance of and to effect the objects of the above-described conspiracy were committed in the Eastern District of Virginia and elsewhere:

a. On or about December 10, 2009, HUDA sent an e-mail from the Eastern District of Virginia to an employee at Elevon stating that GALLANT PHARMA sold “commodity type items”, including the following “sample list of items”:

Compression garments - \$100-\$200
Plastic Surgery healing kits - \$120-\$150
Breast wrap healing patches - \$50-\$75
Elevation pillows - \$50-\$100
Cellulite Reduction creams and treatments - \$50-\$1500
Home beauty devices - \$300-\$1000
Scar Reduction creams \$50-\$80
Consultation gowns and robes \$80-\$150

b. On or about April 15, 2010, HUDA signed an Elevon merchant application form, representing that GALLANT PHARMA sold “Medical supplies, creams, patches.” HUDA represented to be “President” and 50% owner of GALLANT PHARMA.

c. On or about February 8, 2011, KHAN sold two vials of misbranded Zometa and one vial of misbranded Gemzar to a customer in Cary, North Carolina, in exchange for \$1,400, and thereby caused misbranded drugs to travel in interstate commerce from the Eastern District of Virginia.

d. On or about March 15, 2011, HUDA sold twenty-three vials of misbranded Botox, five vials of Juvaderm Ultra 3, four vials of Juvaderm Ultra 4, and five vials of Radiesse to SARRAF, in the Eastern District of Virginia, in exchange for \$8,560.

e. On or about April 4, 2011, HUDA telephoned Elevon from the Eastern District of Virginia and represented that GALLANT PHARMA was “a broker between medical suppliers.”

f. On or about April 6, 2011, HUDA telephoned Elevon from the Eastern District of Virginia and stated that Gallant Pharma was selling the same products as when the Elevon account was established. HUDA represented that Gallant Pharma had added some “skin care products” and was considering a client request to begin selling medical equipment.

g. On or about May 18, 2011, DURR sold five vials of misbranded Eloxatin to Dr. TE in Natick, Massachusetts, in exchange for \$4,250, and thereby caused misbranded drugs to travel in interstate commerce from the Eastern District of Virginia.

h. On or about June 14, 2011, WACHNA sold two vials of misbranded Botox to Dr. RP in Winter Park, Florida, in exchange for \$1,548, and thereby caused misbranded drugs to travel in interstate commerce from the Eastern District of Virginia.

i. On or about June 23, 2011, WHITEHEAD sold six vials of misbranded Alimta to Dr. AS in Bloomfield Hills, Michigan, in exchange for \$2,490, and thereby caused misbranded drugs to travel in interstate commerce from the Eastern District of Virginia.

j. On or about August 23, 2011, CORONITI sold five vials of misbranded Eloxatin to Dr. EA in Mt. Carmel, Pennsylvania, in exchange for \$3,500, and thereby caused misbranded drugs to travel in interstate commerce from the Eastern District of Virginia.

k. On or about September 15, 2011, ROCHELLE sold three vials of misbranded Zometa and four vials of misbranded Gemzar to Dr. DP in Oakland, California, in exchange for \$2,775, and thereby caused misbranded drugs to travel in interstate commerce from the Eastern District of Virginia.

l. On or about September 19, 2011, KHAN and AMINZADA sent a string of e-mails regarding KHAN’s request that AMINZADA mail misbranded drugs from Canada to the Eastern District of Virginia. KHAN instructed AMINZADA:

Bro . . . you take the products to Canada Post and mail it with tracking. That's all. It's very simple. There is a 2 day (if sending cold chain products) and a 4 day delivery. Only put 10 to 20 units per box so the value of the box does not exceed 10k. For the description, simply write "Medical Devices." For the value of the merchandise, put \$100.00.

In reply, AMINZADA asked: "who do we write as a shipper as we don't have pharma license and telephone number." KHAN instructed: "Just put Royal Canadian Imports. In the last 2 years, not a single box has been seized by US Customs . . . so don't worry. For phone number, just put your employee's cell phone number." AMINZADA then asked whether he could instead mail the misbranded drugs to KHAN in the "bahamas". In reply, KHAN stated: "No good bro. Virginia."

m. On or about September 21, 2011, KHAN sent an e-mail to WHITEHEAD explaining why a prescription drug sent from the Eastern District of Virginia to a doctor in Michigan contained a sticker stating "For Clinical Trial":

Hello Harvey, Here is the explanation from my supplier. This makes perfect sense. See below:

The Roche agent cannot usually export Mabthera's, but if they add a small sticker to the vial stating, 'For Clinical Trial', then Roche main office does not mind them selling the products for export. This is only for the Mabthera's. The products are not at all intended for clinical trial as you can see from the Certificate of Analysis. It is a simple small stick-on sticker that the agent has to place on the vial before they can export it. A real clinical trial pack, as you know, does not even come with an outer packaging; it is simply the vial with imprinted onto the vial 'For Clinical Trial Number 12345' which carries the trial number and the address where the trial is taking place.

n. On or about September 23, 2011, KHAN mailed ninety-eight (98) units of misbranded Alimta 100mg obtained from AMINZADA from Canada to the Eastern District of Virginia, which were received by HUDA and MALLICK on or about September 25, 2011.

o. On or about September 26, 2011, an unindicted co-conspirator in the United Kingdom sent an e-mail to KHAN and another unindicted co-conspirator, stating in part: "Please find attached the royal mail information for your order of Botox. Please can you confirm receipt

of the order.” The e-mail attached a pdf document, which depicted two Royal Mail “Despatch Receipts” containing information on thirteen (13) shipments. The top of each Despatch Receipt, in the “Delivery address” column, contained SARRAF’s name and the address of SARRAF’s medical practice in McLean, Virginia, in the Eastern District of Virginia. The subsequent lines in the “Delivery address” column contained handwritten quotation marks.

p. On or about September 26, 2011, HUDA replied to an e-mail from KHAN, forwarding an e-mail exchange between KHAN and unindicted co-conspirators in the United Kingdom. On September 23, 2011, an unindicted co-conspirator in the United Kingdom had written to KHAN, in relevant part:

I am writing with regard to your order for Hydrocortistab which we have been discussing. Due to the product being a prescription only medication, it will not be possible for us to ship the product to the US at all. With Botox and Dysport it is possible as they can be purchased without a prescription, but, with prescription only medication, especially going into America, we need an actual prescription for the product to pass through customs.

In the forwarding message, KHAN wrote: “We’ll have to get the HC through [an unindicted co-conspirator]. He said he should be able to get it.” In reply, HUDA wrote: “Let me know when the HC is expected.”

q. On or about September 27, 2011, KHAN sent an e-mail to WHITEHEAD, DURR, HUDA, and ROCHELLE, with the subject line “FW: Alimta Photos.” The e-mail read:

Hello all, Alimta seems to be a problem sourcing out of Europe in the short term. There is Turkish product available and I have attached the photos. Please let me know your thoughts. If you and your clients are okay with this packaging, I can source it immediately.

The e-mail contained photographs of product packaging and labels, which were written in a language other than English.

r. On or about November 19, 2011, MALLICK sent an e-mail to KHAN. The subject line was “Avastin pic” and the signature line of the e-mail read “Sent from my HTC

smartphone on the Now Network from Sprint.” A photograph was attached to the e-mail, and the photograph depicted a label that contained writing in a language other than English.

s. On or about February 29, 2012, MALLICK negotiated a check in the amount of \$21,353.31 from a Capital One Bank account in Arlington, Virginia, in the Eastern District of Virginia, held in the name of DEEBA MALLICK, made payable to Mercedes-Benz of Alexandria, Virginia, in the Eastern District of Virginia.

t. On or about June 6, 2012, HUDA negotiated a check in the amount of \$10,800 from a Bank of Nova Scotia account held in the name of GALLANT PHARMA INTERNATIONAL INC., made payable to J&H LLC in Springfield, Virginia, in the Eastern District of Virginia.

u. On or about June 15, 2012, HUDA entered into a lease with J&H LLC and thereby rented office space for GALLANT PHARMA in Springfield, Virginia, in the Eastern District of Virginia.

v. On or about August 10, 2012, SARRAF received ten (10) packages on behalf of GALLANT PHARMA at his medical practice in McLean, Virginia, in the Eastern District of Virginia. The packages were sent from the United Kingdom via Royal Mail and were delivered by the USPS. The packages were addressed to SARRAF and the shipping documents indicated that the packages contained “medical instruments” with a declared value of 500 GBP.

w. On or about August 10, 2012, an unindicted co-conspirator retrieved the aforementioned packages from SARRAF’s medical practice in McLean, Virginia, in the Eastern District of Virginia, on behalf of GALLANT PHARMA.

(All in violation of Title 18, United States Code, Section 371).

COUNTS 2-3

(18 U.S.C. § 545 – Importation Contrary to Law)

THE GRAND JURY FURTHER CHARGES THAT:

48. The factual allegations contained in Paragraphs 34 through 47 are re-alleged and incorporated as if set forth here in their entirety.

49. On or about the dates set forth below, in the Eastern District of Virginia and elsewhere, the defendants listed below did fraudulently and knowingly import and bring into the United States merchandise contrary to law, and receive, conceal, buy, sell, and facilitate the transportation, concealment, and sale of, such merchandise after importation, knowing such merchandise to have been imported and brought into the United States contrary to law, in that the merchandise was a misbranded drug in violation of 21 U.S.C. § 331(a).

<i>Count</i>	<i>Approximate Date</i>	<i>Merchandise</i>	<i>Defendants</i>
2	September 23, 2011	Misbranded Alimta from AMINZADA, sent from Canada by KHAN	GALLANT PHARMA, TALIB KHAN, SYED HUDA, DEEBA MALLICK, MIRWAISS AMINZADA, and ANOUSHIRVAN R. SARRAF
3	September 26, 2011	Misbranded Botox sent from the United Kingdom by an unindicted co-conspirator	GALLANT PHARMA, TALIB KHAN, SYED HUDA, DEEBA MALLICK, and ANOUSHIRVAN R. SARRAF

(All in violation of Title 18, United States Code, Sections 545 and 2).

COUNTS 4-8

(21 U.S.C. § 331(a) and 333(a)(2) – Introducing Misbranded Drugs Into Interstate Commerce)

THE GRAND JURY FURTHER CHARGES THAT:

50. The factual allegations contained in Paragraphs 34 through 47 are re-alleged and incorporated as if set forth here in their entirety.

51. On or about the dates listed below, in the Eastern District of Virginia and elsewhere, defendants

**GALLANT PHARMA,
TALIB KHAN,
SYED HUDA,
DEEBA MALLICK,
MUNAJJ ROCHELLE,
ROBERT WACHNA,
HARVEY WHITEHEAD,
PATRICIA DURR, and
LISA CORONITI,**

with the intent to defraud and mislead, introduced, delivered for introduction, and caused the introduction and delivery for introduction into interstate commerce, from the Eastern District of Virginia to the locations listed below, the indicated drugs that were misbranded as defined in Title 21, United States Code, Section 352(f)(1), in that the labeling did not bear adequate directions for use.

<i>Count</i>	<i>Approximate Date</i>	<i>Description of Introduction</i>
4	May 18, 2011	Shipment of five vials of misbranded Eloxatin to Dr. TE in Natick, Massachusetts, in exchange for \$4,250

<i>Count</i>	<i>Approximate Date</i>	<i>Description of Introduction</i>
5	June 14, 2011	Shipment of two vials of misbranded Botox to Dr. RP in Winter Park, Florida, in exchange for \$1,548
6	June 23, 2011	Shipment of six vials of misbranded Alimta to Dr. AS in Bloomfield Hills, Michigan, in exchange for \$2,490
7	August 23, 2011	Shipment of five vials of Eloxatin to Dr. EA in Mt. Carmel, Pennsylvania, in exchange for \$3,500
8	September 15, 2011	Shipment of three vials of misbranded Zometa and four vials of misbranded Gemzar to Dr. DP in Oakland, California, in exchange for \$2,775

(All in violation of Title 21, United States Code, Sections 331(a) and 333(a)(2), and Title 18, United States Code, Section 2).

COUNTS 9-13

(21 U.S.C. § 331(t) – Unlicensed Wholesale Distribution of Prescription Drugs)

THE GRAND JURY FURTHER CHARGES THAT:

52. The factual allegations contained in Paragraphs 34 through 47 are re-alleged and incorporated as if set forth here in their entirety.

53. On or about the dates listed below, in the Eastern District of Virginia, defendants

GALLANT PHARMA,

TALIB KHAN,

SYED HUDA,

DEEBA MALLICK,

MUNAJJ ROCHELLE,

ROBERT WACHNA,

HARVEY WHITEHEAD,

PATRICIA DURR, and

LISA CORONITI,

did knowingly engage in the wholesale distribution in interstate commerce of prescription drugs without being licensed by the Commonwealth of Virginia.

<i>Count</i>	<i>Approximate Date</i>	<i>Description of Unlicensed Distribution</i>
9	May 18, 2011	Shipment of five vials of misbranded Eloxatin to Dr. TE in Natick, Massachusetts, in exchange for \$4,250
10	June 14, 2011	Shipment of two vials of misbranded Botox to Dr. RP in Winter Park, Florida, in exchange for \$1,548
11	June 23, 2011	Shipment of six vials of misbranded Alimta to Dr. AS in Bloomfield Hills, Michigan, in exchange for \$2,490
12	August 23, 2011	Shipment of five vials of Eloxatin to Dr. EA in Mt. Carmel, Pennsylvania, in exchange for \$3,500

<i>Count</i>	<i>Approximate Date</i>	<i>Description of Unlicensed Distribution</i>
13	September 15, 2011	Shipment of three vials of misbranded Zometa and four vials of misbranded Gemzar to Dr. DP in Oakland, California, in exchange for \$2,775

(All in violation of Title 21, United States Code, Sections 331(t), 333(b)(1)(D), and 353(e)(2)(A), and Title 18, United States Code, Section 2).

COUNTS 14-15

(18 U.S.C. § 1343 – Wire Fraud)

THE GRAND JURY FURTHER CHARGES THAT:

54. The factual allegations contained in Paragraphs 34 through 47 are re-alleged and incorporated as if set forth here in their entirety.

Object of the Scheme and Artifice to Defraud

55. The objects of the Conspiracy charged in paragraph 33 of Count 1 are re-alleged and incorporated as if set forth here in their entirety to describe the objects of the scheme and artifice to defraud.

Ways, Manner, and Means of the Scheme and Artifice to Defraud

56. The Manner and Means of the Conspiracy section of Count 1 is re-alleged and incorporated as if set forth here in its entirety to describe the scheme and artifice.

Execution of the Scheme and Artifice to Defraud

57. On or about the dates listed below, in the Eastern District of Virginia and elsewhere, defendants **GALLANT PHARMA** and **SYED HUDA**, for the purpose of executing and attempting to execute the aforesaid scheme and artifice to defraud, did knowingly transmit and cause to be transmitted wire communications in interstate and foreign commerce, as indicated below.

<i>Count</i>	<i>Approximate Date</i>	<i>Wire Communication</i>
14	December 10, 2009	E-mail from SYED HUDA to Elevon, including list of sample “commodity type” items sold by GALLANT PHARMA
15	April 4, 2011	Telephone call from SYED HUDA to Elevon, representing that GALLANT PHARMA was “a broker between medical suppliers.”

(All in violation of Title 18, United States Code, Section 1343)

COUNTS 16-17

(18 U.S.C. § 1957(a) – Monetary Transaction With Criminally Derived Proceeds)

THE GRAND JURY FURTHER CHARGES THAT:

58. The factual allegations contained in Paragraphs 34 through 47 are re-alleged and incorporated as if set forth here in their entirety.

59. On or about the dates listed below, in the Eastern District of Virginia, the Defendants listed below did knowingly engage and attempt to engage in a monetary transaction by through and to a financial institution, affecting interstate and foreign commerce, in criminally derived property of a value greater than \$10,000, such property having been derived from specified unlawful activity, that is, importation contrary to law, in violation of Title 18, United States Code, Section 545, and wire fraud, in violation of Title 18, United States Code, Section 1343.

<i>Count</i>	<i>Date</i>	<i>Transfer</i>	<i>Defendants</i>
16	February 29, 2012	Negotiation of check number 133 in the amount of \$21,353.31, drawn on Capital One account number 7773206376 in the name of DEEBA MALLICK, made payable to Mercedes-Benz of Alexandria, Virginia.	DEEBA MALLICK
17	June 6, 2012	Negotiation of check number 240 in the amount of USD \$10,800, drawn on Bank of Nova Scotia account no. 0041416, in the name of GALLANT PHARMA International Inc., made payable to J&H LLC.	GALLANT PHARMA and SYED HUDA

(All in violation of Title 18, United States Code, Section 1957(a)).

NOTICE OF FORFEITURE

(18 U.S.C. § 981(a)(1)(C); 18 U.S.C. § 982(a)(1); 28 U.S.C. § 2461(c))

1. The allegations contained in Counts 1-3 and 14-17 of this Indictment are hereby realleged and incorporated by reference for the purpose of alleging forfeiture.
2. Pursuant to Federal Rule of Criminal Procedure 32.2(a), the United States of America gives notice to the Defendants that, in the event of a conviction of any of the offenses charged in Counts 1-3 and 14-17 of this Indictment, the United States intends to forfeit the property further described in this NOTICE OF FORFEITURE.
3. A defendant who is convicted of an offense in violation of 18 U.S.C. §§ 545 or 1343, or a conspiracy to violate 18 U.S.C. §§ 545 or 1343, shall forfeit to the United States of America, pursuant to 18 U.S.C. § 981(a)(1)(C) and 28 U.S.C. § 2461(c), any property, real or personal, which constitutes or is derived from proceeds traceable to such violation(s).
4. A defendant who is convicted of an offense in violation of 18 U.S.C. § 1957 shall forfeit to the United States of America, pursuant to 18 U.S.C. § 982(a)(1), any property, real or personal, involved in such violation, or any property traceable to such property.
5. The property to be forfeited includes, but is not limited to, the following:
 - a. \$3.3 million in United States dollars;
 - b. Bank of Nova Scotia account no. 0041416, in the name of GALLANT PHARMA INTERNATIONAL INC.;
 - c. Toronto Dominion Bank account no. 02017305209, in the name of GALLANT PHARMA INTERNATIONAL INC.;
 - d. Capital One Bank account no. 7773206376, in the name of DEEBA MALLICK;

- e. 2012 Mercedes-Benz ML350W4 (VIN 4JGDA5HB6CA046380); and
- f. 315 Sapphire Beach Condos, St. Lawrence Gap, Christ Church, Barbados.

6. If any of the property described above, as a result of any act or omission of any defendant,

- a. cannot be located upon the exercise of due diligence;
- b. has been transferred or sold to, or deposited with, a third party;
- c. has been placed beyond the jurisdiction of the court;
- d. has been substantially diminished in value; or
- e. has been commingled with other property which cannot be divided without difficulty,

the United States of America shall be entitled to forfeiture of substitute property pursuant to Title 21, United States Code, Section 853(p), as incorporated by Title 18, United States Code, Sections 982(b)(1) and Title 28, United States Code, Section 2461(c).

(All pursuant to 18 U.S.C. § 981(a)(1)(C) and § 982(a)(1), and 28 U.S.C. § 2461(c))

NEIL H. MACBRIDE
UNITED STATES ATTORNEY



LINDSAY A. KELLY
ASSISTANT UNITED STATES ATTORNEY

A TRUE BILL:

Pursuant to the U.S. Government Act,
the original of this page has been filed
under seal at the Clerk's Office.

Foreperson of the Grand Jury